IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.

Introduction and Summary

Plaintiffs in the wave of cases referenced in Exhibit A to Defendants' accompanying motion have retained Dr. Bobby Shull to offer a number of opinions that are beyond his expertise as a urogynecologist and/or that are unreliable, irrelevant, and/or otherwise improper. For the reasons set forth below the Court should preclude Dr. Shull from:

- Criticizing Defendant Ethicon, Inc.'s ("Ethicon's") warnings and labels, because he is not qualified to do so, and his opinions are irrelevant;
- Suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable;
- Providing design and development opinions, because such opinions are beyond his expertise;
- Speculating about the duties owed by a medical device manufacturer, such as research/testing, adverse event reporting, and training, because such opinions are irrelevant and beyond his expertise; and

- Testifying about other matters that are outside of his expertise as a urogynecologist and/or that are otherwise improper.

All of these opinions are inadmissible under Rules 702 and 703 and the *Daubert* standard governing expert witness testimony.

BACKGROUND

Several Plaintiffs in Wave 3 have designated Dr. Shull to provide general and case-specific expert opinions addressing Prolift and Prolift +M (collectively "Prolift"). (Ex. B, Prolift Report).[1] Dr. Shull is a urogynecologist in Temple, Texas. (Ex. A to Ex. B, Prolift Report, curriculum vitae). Although Dr. Shull uses TVT for the surgical treatment of stress urinary incontinence, he has never tried using Prolift for the surgical treatment of pelvic organ prolapse. (Ex. E, Shull Mar. 10, 2016 Dep. Tr. 13:16-22; Ex. F, Shull Mar. 15, 2016 Dep. Tr. 39:19-21). Dr. Shull is not personally critical of all uses of polypropylene mesh for pelvic reconstruction, but he prefers to use native tissue repair. (*Id.* at 45:8-11, 49:23-50:9).

LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should exclude Dr. Shull's warning opinions, because he is not qualified and certain of his opinions are irrelevant.

Dr. Shull has freely admitted that he is not an expert in developing warnings and labels for medical devices: "I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area." (Ex. G, Shull Feb. 2013 Dep. Tr. 115:1-7; *see also id.* at 64:12-16, 348:11-350:25). Nonetheless,

[1] Exhibits cited in this brief were filed as exhibits to Defendants' Wave 1 motion to exclude Dr. Shull. *See* Doc. 2052.

Dr. Shull is prepared to offer opinions about the adequacy of the warnings for Prolift. (Ex. B, Prolift Report at 3, 10).

Based on this same testimony and his failure to address what the product warnings should have said, this Court has precluded Dr. Shull from testifying about the adequacy of product warnings for other pelvic mesh medical devices. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). Noting that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise about what information should or should not be included in an IFU," the Court has further found that Dr. Shull "does not possess [such] additional expertise." *In re: Ethicon, Inc. Pelvic Repair Sys. Produc. Liab. Litig.*, 2016 WL 458220, at *3 (S.D. W. Va. Sept. 1, 2016). The Court should follow and apply those rulings to this case for the same reasons and preclude Dr. Shull from expressing any opinions about the adequacy of the warnings for Prolift.

This includes preventing Dr. Shull from testifying that "Ethicon did not inform doctors as to which patients were poor candidates for the Prolift procedure." (Ex. B, Prolift Report at 12). To the extent that Dr. Shull intends to testify about those patient populations of which each respective Plaintiff is not a member, any such testimony is irrelevant and unhelpful to the jury and therefore inadmissible. *See* Fed. R. Evid. 402, 702. Moreover, Dr. Shull's opinions are merely a narrative summary of Ethicon documents (*see, e.g.*, Ex. B, Prolift Report at 12), and as this Court and many others have recognized, "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). The Court should preclude Dr. Shull from doing so here.

In *Huskey*, Dr. Rosenzweig sought to testify that Ethicon inappropriately promoted the product as appropriate for all patients. 29 F. Supp. 3d at 705. This Court, however, found that "much of this opinion is not relevant to [the plaintiff's] case and should be excluded." *Id.* The Court went further and also precluded Dr. Rosenzweig from testifying about the appropriateness of the product to the plaintiff's specific population. *See id.* The Court reasoned that Dr. Rosenzweig's opinion was merely based upon his review of a document, and "[t]he jury is capable of reading that document itself." *Id.*

Based on the statements set forth on page 12 of Dr. Shull's reports, Ethicon anticipates that Plaintiffs will attempt to elicit the same type of testimony from Dr. Shull that the plaintiffs in *Huskey* sought to elicit from Dr. Rosenzweig. For the same reasons as *Huskey*, the Court should preclude Dr. Shull from offering such testimony here.

II. The Court should preclude Dr. Shull from suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable.

In his reports, Dr. Shull states that "[s]maller pore, heavier weight meshes, like Gynemesh PS, are thought to intensify" adverse reactions as compared to lighter weight, more macroporous meshes. (Ex. B, Prolift Report at 7). Ethicon challenged this same assertion in its Wave 1 briefing on the basis that it perceived that Dr. Shull was unreliably suggesting that a device with larger pore, lighter weight mesh would offer a safer, feasible alternative to Prolift. The Court, however, found that Dr. Shull's afore-quoted statement is "not about the overall balance between safety and efficacy or the appropriateness of an alternative design; Dr. Shull was merely opining on adverse reactions." *In re: Ethicon*, 2016 WL 458220, at *3.

If, in fact, Dr. Shull has not disclosed any opinions that suitable alternative device designs were available, then Dr. Shull's opinions about other devices or potential devices are not

relevant. It is one thing for Dr. Shull to provide opinions about adverse reactions caused by Prolift. On the other hand, Ethicon would be prejudiced should Dr. Shull be allowed to compare Prolift's adverse reactions to the adverse reactions in other medical devices if Dr. Shull is not offering an opinion (much less a reliable opinion) that those other devices were a suitable alternative.

Should the Court construe Dr. Shull's assertion as suggesting that other synthetic mesh devices offered safer, feasible alternatives to Prolift, the Court should preclude any such testimony as unreliable. Even if a device with lighter-weight/more macroporous mesh would have led to few complications, neither Dr. Shull nor any other expert can reliably show that such a device would have been as effective as Prolift in treating pelvic organ prolapse.

In *Conklin v. Novartis Pharmas. Corp*, 2012 WL 4127295 (E.D. Tex. 2012), the district court concluded that an expert could not opine about an allegedly safer alternative design as required by Texas law because there was no evidence as to the alternative's utility. *Conklin* illustrated this by setting out the expert's premises and conclusions:

> **Premise:** Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause [bone disease]
>
> **Premise:** Other studies show that less Zometa will result in less [bone disease].
>
> **Conclusion:** A regimen using less Zometa will help treat cancer-related bone conditions.
>
> This is a classic logical fallacy—an irrelevant conclusion.

Id. at *9. The court found an impermissible "analytical gap," because there was no evidence that reducing the dosage would not only reduce the side effect but would "also be effective at fighting cancer-related diseases." *Id*. at *10.

Here, the same analytical gap exists. Dr. Shull has suggested that the mesh in Prolift would have fewer adverse reactions if it had been made of larger pore, lighter weight mesh. But Dr. Shull points to no studies, testing, or other scientific evidence whatsoever that those devices would have been equally effective as a treatment for prolapse if the mesh had those characteristics. Nor does Dr. Shull point to any evidence that, had the mesh had such characteristics, there would not be an increased risk of other adverse events. Like the opinion stricken in *Conklin*, Dr. Shull's opinions are supported by nothing more than the "naked conclusion" of the expert. That is not enough.

Dr. Shull cannot—and does not—identify the polypropylene volume at which efficacy can be obtained and adverse events avoided. At most, he merely suggests that some form of mesh may exist in which the volume of polypropylene is low enough to avoid adverse events but high enough to be sufficiently effective. What that volume is, he does not know. And whether this hypothetical alternative exists, he does not know. In this context, his opinions are entirely speculative, and they should be excluded.

III. The Court should preclude Dr. Shull from providing design and development opinions, because he is unqualified to do so.

Dr. Shull has no experience in the design, development, or manufacturing process of any medical devices, and he never received any documents from Ethicon referencing the design and development of its devices. *See* Ex. F, Shull Mar. 15, 2016 Dep. Tr. at 63:12-14, 82:5-12. Dr. Shull, nevertheless, asserts in his reports that "[f]rom a clinical perspective, Ethicon did not exercise due diligence in the design and development of the" devices at issue. (Ex. B, Prolift Report at 3). Aside from the fact that this interjects an irrelevant, improper legal conclusion concerning "due diligence," which is a phrase that is vague, ambiguous, and without any meaning as used in this context, Dr. Shull cannot purport to weigh in on these topics "[f]rom a

clinical perspective," because the design and development of pelvic mesh medical devices is beyond his expertise as a pelvic surgeon.

This Court has previously precluded Dr. Shull and other pelvic surgeons from offering similar opinions. *See, e.g., Cisson*, 948 F. Supp. 2d at 612-13 (precluding Dr. Shull from providing similar testimony); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561-62 (S.D. W. Va. 2014) (finding that another pelvic surgeon, Dr. Blaivas, was not qualified to testify about product design). In, adjudicating Ethicon's challenge to these same opinions in the Wave 1 cases, the Court indicated that it did not construe Dr. Shull's reports as "express[ing] any opinions about the process of designing a product." *In re: Ethicon*, 2016 WL 4582220, at *3. Because Dr. Shull's reports in this wave of cases are identical to his reports in the Wave 3 cases, the Court should make the same finding here. Alternatively, Ethicon respectfully requests that the Court preclude Dr. Shull from providing such opinions on the basis that he is unqualified to do so.

IV. The Court should not allow Dr. Shull to speculate about the duties of a medical device manufacturer.

Because Dr. Shull is not qualified to provide expert opinions about what duties Ethicon owed as a manufacturer of FDA-cleared medical devices, the Court should preclude him from offering opinions set forth throughout his report that criticizes Ethicon for allegedly failing to comply with certain legal duties allegedly owed by a medical device manufacturer.

A. Research/Testing

In his reports, Dr. Shull faults Ethicon for allegedly not performing certain testing and conducting studies. (*See, e.g.*, Ex. B, Prolift Report at 3, 24-26). The Court should exclude these opinions, which are of questionable relevance, because Dr. Shull is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

A lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) ("[A] product that is not defective and has not been tested at all remains free of a defect"). The "failure to test" claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were somehow relevant,[2] Dr. Shull does not have specialized knowledge about the testing that medical device manufacturers like Ethicon supposedly should have performed. Dr. Shull lacks a basic familiarity with product testing. (Ex. G. Shull Feb. 2013 Dep. Tr. 81:10-21, 138:6-17, 144:22-145:1). He acknowledged that he has no experience in developing medical devices. (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 63:12-14, 82:5-7). Dr. Shull's resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Dr. Shull has no relevant experience, he is unable to identify a single rule or regulation that would require Defendants to conduct different testing. (*See* Ex. B, Prolift Report at 3, 24-26). Moreover, Dr. Shull does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal, subjective belief. *See Daubert*, 509 U.S. at 590 ("[T]he word 'knowledge' [in Rule 702] connotes more than subjective belief or unsupported speculation").

[2] *See In re: Ethicon*, 2016 WL 4582220, at *5 ("I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research . . .").

In *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015), this Court found that "because Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted." *See also Huskey*, 29 F. Supp. 3d at 723 (finding that "there is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake"); Ex. H, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014) ("Whether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct"). For these same reasons, the Court should preclude Dr. Shull from offering such testimony here.

B. Adverse Event Reporting

Dr. Shull also claims that "Ethicon did not systematically monitor their products or evaluate physician feedback." (Ex. B, Prolift Report at 3). Dr. Shull's experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, 2001 WL 454586, at *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

Not surprisingly, because Shull has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to collect and report adverse events in the manner he vaguely suggests it should have (whatever that might be). In fact, Dr. Shull does not identify *any* basis or reason for his opinion that Ethicon did not have an appropriate monitoring system in

place beyond the bald, unreliable assertion that "[i]f they had one, it wasn't obvious to the physicians who were using the products." (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 90:1-5).

As the foregoing statement shows, Dr. Shull's general report does not describe Ethicon's monitoring system or its purported deficiencies, and the opinion is therefore total speculation. Furthermore, he not in a position to know what was obvious to other physicians, and that opinion is also based on pure speculation and his unsupported personal belief. The Court should exclude his opinion on that basis. *See Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (finding that expert provided no basis for opinions, rendering them inadmissible "personal opinion").

C. Training

Dr. Shull claims that Ethicon generally did not provide appropriate training to physicians. (Ex. B, Prolift Report at 3). First, Plaintiffs cannot show that Ethicon owed any duty to train physicians. *See, e.g., Woodhouse v. Sanofi-Aventis U.S. L.L.C.*, 2011 WL 3666595, at *3 (W.D. Tex. June 23, 2011); *Adeyinka v. Yankee Fiber Control, Inc.*, 564 F. Supp. 2d 265, 286 (S.D. N.Y. 2008); *Lemon v. Anonymous Physician*, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005). Even if Ethicon owed any such duty (which it does not), physician training "seem[s] to say very little about the state of the product (i.e., whether or not it was defective) when it went on the market." *In re: Ethicon*, 2016 WL 4582220, at *5.

In any event, Dr. Shull, as a urogynecologist with no experience working for a medical device manufacturer, is not qualified to opine about the level of training that a manufacturer is required to provide. Dr. Shull does not know what FDA rules, if any, apply to this subject, what the consequences of failing to comply with FDA rules are, and/or what the legal effect of

noncompliance is. Further, Dr. Shull's criticism of Ethicon's training is unreliable, because he does not explain the basis for his opinions.[3]

V. The Court should prevent Dr. Shull from providing general opinions about Prolene Soft.

Dr. Shull has prepared general reports in these waves of cases only for Prolift and Prosima. Although one of the Plaintiffs in Exhibit A to Defendants' motion, Bonita Taylor, designated Dr. Shull a general causation expert, she was not implanted with any of these devices. Instead, she was implanted with the Prolene Soft device. No. 2:12-cv-02601, Doc. 3, ¶8. Because Plaintiffs have not disclosed any opinions of Dr. Shull related to the Prolene Soft, they should not be allowed to elicit opinions from him about this product. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *Lewis v. Ethicon, Inc.*, 2014 WL 186872, at *17 (S.D. W. Va. Jan 15, 2015) ("Under Rule 26, expert reports must contain 'a complete statement of all opinions the witness will express and the basis and reasons for them'").

VI. The Court should not allow other opinions beyond Dr. Shull's expertise.

Finally, consistent with its prior rulings, the Court should preclude Dr. Shull from: (a) speculating about Ethicon's alleged knowledge and corporate conduct;[4] (b) testifying about a medical condition that a Plaintiff's medical expert has not competently testified that the Plaintiff has sustained or likely will sustain; (c) stating legal conclusions;[5] (d) accusing Ethicon of failing to comply with FDA requirements;[6] (e) providing marketing opinions;[7] and (f) setting forth a

[3] Dr. Shull's opinions are not based on his personal experience, because he has never undertaken any training from Ethicon concerning use of its devices. (Shull Mar. 15, 2015 Dep. Tr. 40:13-18).

[4] *See, e.g.*, Ex. B, Prolift Report at 9-13, 24-26, 28-44.

[5] *See id.* at 3.

[6] *See id.* at 10.

[7] *See id.* at 3, 13.

narrative summary of Ethicon documents.[8] *See, e.g.*, *In re: Ethicon*, 2016 WL 4582220, at *4-5; *Cisson*, 948 F. Supp. 2d at 611, 614; *Huskey*, 29 F. Supp. 3d at 703.

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Shull's testimony in these cases.

Respectfully Submitted,

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[8] *See, e.g., id.* at 11-13, 29-44.

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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